

REPLY TO FINAL OFFICE ACTION

U.S. Serial No.: 10/724,292

Filing Date: 1 December 2003

Atty. Dkt. No. 061537-0036

**REMARKS**

***The Claims are Not Indefinite***

The Office Action of 22 April 2010 rejected claims 22 and 24 as allegedly indefinite. Applicants assert that the amendments to the specification and claims render moot the indefiniteness rejection. Specifically, the application contains a description of the contents of ATCC Deposit No. PTA-10532. In addition, claim 24 has been amended to correct antecedent basis. Applicants respectfully request reconsideration and withdrawal of the indefiniteness rejection.

***The Claims are Fully Enabled***

The Office Action of 22 April 2010 rejected claims 22 and 24 because the specification allegedly fails to enable the claimed invention. Applicants respectfully disagree and assert that the specification enables the full scope of the presently claimed invention.

Applicants have amended the claims to better capture the envisioned commercial embodiments and assert that the amendments render moot the enablement rejection. Specifically, claim 24 is directed towards hepatic fibrosis not towards “various fibrotic disorders.” Applicants assert that the specification provides ample guidance and evidence that the target of the administered viral particles is primarily and predominantly the liver. *See* pages 12-16 of the specification.

In addition, this same passage in the specification provides ample guidance to one of skill in the art for delivering the target to hepatocytes. The Examiner cites Deonarian for the supposition that “one of the biggest problems hampering successful gene therapy in the ‘ability to target a gene to a specific population of cells and express it at adequate levels for a long enough period of time.’” *Office Action of 22 April 2010, page 5* (quoting Deonarian, M., *Expert Opin. Ther. Pat.*, 8:53-69(1998)). Applicants assert that the specification demonstrates that the specifically claimed composition comprising the claimed viral particles targets the liver almost exclusively. Applicants assert that the specification specifically addresses the Office Action’s concerns regarding targeting a specific population of cells when it discusses transduction rates of less than 1% in all organs examined other than the liver.

In making the rejection, the Examiner also states that the claims “encompass using nucleotide sequences involving various therapeutic proteins . . . .” *Office Action of 22 April 2010, page 7*. Applicants

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respectfully disagree that the previous version of the claims read on using various therapeutic proteins. Nonetheless, Applicants assert that the claim amendments render this portion of the enablement rejection moot as the claims now read on the specific vector contained in ATCC Deposit No. PTA-10532.

Applicants assert that the specification is fully enabling with respect to the claims as they currently stand, such that one of skill in the art would be able to practice the full scope of the claimed invention without undue experimentation. Applicants respectfully request reconsideration and withdrawal of the enablement rejection.

CONCLUSION

Applicants have amended the specification and claims to better capture the envisioned commercial embodiments and to insert deposit information into the specification. Applicants assert that the amendments do not introduce new matter. In addition, Applicants assert that the amendments to the claims and specification render moot the remaining rejections.

The Examiner is invited to contact the undersigned at the telephone number listed below if discussion of any remaining issues would better advance prosecution.

Respectfully submitted,

Date 2 September 2010 By /Todd B. Buck/

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